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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,935	01/30/2001	Gerardo R. Vasta	4115-137 CIP	9125

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,935

Applicant(s)

VASTA ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9-13, 15-18 and 20-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-13, 15-18, and 20-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the amendment filed October 2, 2003. Applicants amendments and arguments have been fully considered but are not sufficient to overcome the present grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.
2. The terminal disclaimer filed on October 2, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,326,485 has been reviewed and is accepted. The terminal disclaimer has been recorded.
3. Claims 2, 3, 15-18, 20, 21, 24-26, 28 and 31 and newly added claims 21, 24-26, 28 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 2 and 16-18 are further indefinite over the recitation of "a nucleic acid sequence of SEQ ID NO: 18". In view of the recitation of "a" and the limitation in claim 18 that the oligonucleotide is one of a pair of PCR primers, it is not clear as to whether this phrase refers to the full length sequence of SEQ ID NO: 18 or to fragments of any length of SEQ ID NO: 18. Similarly, claims 3 and 20, are indefinite over the recitation of "a nucleic acid sequence". If Applicant intends to claim fragments of these sequences, then the claims should be amended to clarify this concept. This rejection now applies to newly added claims 21, 24-26 and 31.

B. Claims 16 and 17 are indefinite and vague because it is not clear as to whether the claims are intended to include the steps of, e.g., amplifying a NTS sequence using primers or digesting DNA with a restriction enzyme or whether these recitations further characterize the isolated nucleic acids. In the former case, the claims should be amended to clarify, for example, "wherein the isolating step comprises..."

C. Claim 15 is indefinite over the recitation of "said nucleic acid sequence" because this phrase lacks proper antecedent basis. While the claim previously refers to a "nucleotide base sequence", the claim does not previously refer to a "nucleic acid sequence."

D. Claim 28 (previously claim 14) is indefinite and unclear over the recitation that the nucleotide base sequence has type I and type II NTS sequences of SEQ ID NO: 24 and 25. Since SEQ ID NO: 24 and SEQ ID NO: 25 are 2 distinct sequences that located at the same position in the NTS, it is unclear as to what is meant by the organism having both of these sequences. For example, it is unclear as to whether the organism has 2 copies of the NTS, comprises either SEQ ID NO: 24 or SEQ ID NO: 25 or comprises some unspecified combination of SEQ ID NO: 24 and 25. Furthermore, the parenthesis should be removed from the claim because it is not clear as to whether the claim intends to refer to any NTS type I or type II sequence or to the specific NTS type I and II sequences of SEQ ID NO: 24 and 25.

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants stated that the previous grounds of rejection have been overcome by the amendments to the claims. However, claims 15-18 were not amended in the response of October 2, 2003. Further, with respect to "A" above, it remains unclear as to whether the claims are intended to be

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limited to the full length sequence of SEQ ID NO: 18 or to sequences that consist of or comprise portions of SEQ ID NO: 18 (e.g. 1 mers, 2 mers etc of SEQ ID NO: 18).

Applicants response did not specifically address the previous grounds of rejection over claim 14. While claim 14 has been cancelled, this rejection now applies to newly added claim 28.

4. **PRIORITY**

It is noted that the present application is entitled to only the present filing date of January 30, 2001 for SEQ ID NO: 8, 9, 12-15, 18, 19, and 23-25.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 9-11, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Robledo (1999, reference AX in the IDS of August 31, 2001).

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus marinus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 1 (see Figure 2). The reference also teaches nucleic acids comprising NTS type I and II sequences (see Figure 3). The nucleic acid of Robledo

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shares extensive sequence identity with SEQ ID NO: 18 and have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of SEQ ID NO: 18 and having a nucleotide sequence comprising a fragments of SEQ ID NO: 18. It is noted that the claims as broadly written are inclusive of oligonucleotides which hybridize under any conditions to a nucleic acid comprising SEQ ID NO: 18 or to a nucleic acid which comprises any fragment of any length of SEQ ID NO: 18 (i.e., a nucleic acid which has one nucleotide of SEQ ID NO: 18 flanked by any number of nucleotides of any identity).

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state that the Robledo does not teach SEQ ID NO: 18 and thereby does not anticipate the claimed invention. However, the claims are not limited to a nucleic acid which consists of SEQ ID NO: 18. Rather, the claims as broadly drawn are inclusive of nucleic acids which hybridize under any conditions (e.g., low stringency conditions) and to any degree (non-specific hybridization) to a nucleic acid comprising any portion of SEQ ID NO: 18. Accordingly, Applicants arguments are not convincing because they are not directed to limitations recited in the claims.

6. Claims 1, 4, 9-11, 13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Marsh (reference AP in the IDS of August 31, 2001).

Marsh teaches isolated nucleic acids comprising the NTS region of *Perkinsus marinus*. In particular, the nucleic acid of Marsh comprises a sequence identical to present SEQ ID NO: 1 (see Figure 1). Marsh also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 4 and 5 and of a length of 21 nucleotides (see page 577). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Marsh have the property of

hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18 and comprise fragments of SEQ ID NO: 1, 2, 3 and 18. Marsh also teaches the nucleic acids so that they may be used as probes (see page 578).

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state that the Marsh does not teach SEQ ID NO: 18, nor SEQ ID NO: 8, 9, 12-15 and thereby does not anticipate the claimed invention. However, the claims are not limited to a nucleic acid which consists of SEQ ID NO: 18. Rather, the claims as broadly drawn are inclusive of nucleic acids which hybridize under any conditions (e.g., low stringency conditions) and to any degree (non-specific hybridization) to a nucleic acid comprising any portion of SEQ ID NO: 18. Accordingly, Applicants arguments are not convincing because they are not directed to limitations recited in the claims.

7. Claims 1, 2, and 4, 9-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Robledo (October 2000/reference AY in the IDS of August 31, 2001).

It is noted that the inventorship of the present application is distinct from the authorship of the Robledo et al reference.

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus atlanticus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 18 (see Figure 2). Robledo also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 8 and 9 and of a length of 20 and 22 nucleotides, respectively (see page 974). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18 and comprise fragments of

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SEQ ID NO: 1, 2, 3 and 18. The reference also teaches methods of making an oligonucleotide comprising SEQ ID NO: 18 wherein said method comprises isolating DNA from a target organism, amplifying the nucleic acids of the NTS region of the target organism using primers, thereby synthesizing NTS nucleic acids comprising a sequence of SEQ ID NO: 18, sequencing said NTS nucleic acids and synthesizing PCR primers for amplifying Perkinsus sequences (see pages 973-974).

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state that the Robledo reference is not prior art to the claimed invention because Applicants have provided a Declaration establishing that the cited publication describes their own work.

The Declaration of Dr. Vasta has been fully considered but is not sufficient to remove the Robledo reference as prior art. The declaration states that Robledo and Coss are "co-inventors of the present application and also co-authors of the cited references, both of which describe our work." However, a 132 Katz-type Declaration must establish the relationship of the application to the publication and therefore must address the absence of inventors on a cited reference. See Ex parte Magner, Long, Ellis and Grinstead, 133 USPQ 404 (BdPatAp&Int 1962). In particular, the 132 Declaration does not address the absence of the inventors Adam G. Marsh and Anita C. Wright from the Robledo et al (2000) reference. If the reference describes the work of Vasta, Robledo and Coss, and describes the work claimed in the present application, it is unclear as to why Marsh and Wright are included as co-inventors of the claimed invention.

8. Claims 1 and 4, 9, and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Robledo (GenBank Accession No. AF140295/NCBI Database, April 17, 2000).

It is noted that the inventorship of the present application is distinct from the authorship of the Robledo et al reference.

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus atlanticus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 18 (see Figure 2). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 18 and comprise fragments of SEQ ID NO: 18.

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state that the Robledo reference is not prior art to the claimed invention because Applicants have provided a Declaration establishing that the cited publication describes their own work.

The Declaration of Dr. Vasta has been fully considered but is not sufficient to remove the Robledo reference as prior art. The declaration states that Dr. Vasta, Robledo and Coss are "co-inventors of the present application and also co-authors of the cited references, both of which describe our work." However, a 132 Katz-type Declaration must establish the relationship of the application to the publication and therefore must address the absence of inventors on a cited reference. See Ex parte Magner, Long, Ellis and Grinstead, 133 USPQ 404 (BdPatAp&Int 1962). In particular, the 132 Declaration does not address the absence of the inventors Adam G. Marsh and Anita C. Wright from the GenBank reference.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robledo (1999/references "AX") in view of Stokes (reference "BA").

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus marinus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 1 (see Figure 2). The reference also teaches nucleic acids comprising NTS type I and II sequences (see Figure 3). The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 18. Robledo teaches using the nucleic acid as a probe to detect *Perkinsus* sequences, but does not teach labeling the nucleic acid.

Stokes teaches labeling nucleic acid probes with digoxigenin to facilitate the detection of oyster pathogens (see, for example, page 351).

In view of the teachings of Stokes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to label the probes of Robledo with

digoxigenin in order to have provided an effective means for facilitating the detection of *Perkinsus* nucleic acids.

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state that claim 1 and all claims depending therefrom have been amended to recite SEQ ID NO: 18 and argue that Robledo does not teach SEQ ID NO: 18. However, the claims are not limited to a nucleic acid which consists of SEQ ID NO: 18. Rather, the claims as broadly drawn are inclusive of nucleic acids which hybridize under any conditions (e.g., low stringency conditions) and to any degree (non-specific hybridization) to a nucleic acid comprising any portion of SEQ ID NO: 18. Accordingly, Applicants arguments are not convincing because they are not directed to limitations recited in the claims. Applicants state that there is no motivation to use SEQ ID NO: 18 in an assay. However, again, claim 13 is not limited to nucleic acids consisting of SEQ ID NO: 18.

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robledo (2000/references "AY") in view of Stokes (reference "BA").

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus atlanticus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 18 (see Figure 2). Robledo also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 8 and 9 and of a length of 20 and 22 nucleotides, respectively (see page 974). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 18. The reference also teaches methods of making an oligonucleotide comprising SEQ ID NO: 18 wherein said method comprises isolating DNA from a target organism, amplifying the nucleic acids of the

NTS region of the target organism using primers, thereby synthesizing NTS nucleic acids comprising a sequence of SEQ ID NO: 18, sequencing said NTS nucleic acids and synthesizing PCR primers for amplifying *Perkinsus* sequences (see pages 973-974). Robledo does not teach labeling the nucleic acid.

Stokes teaches labeling nucleic acid probes with digoxigenin to facilitate the detection of oyster pathogens (see, for example, page 351).

In view of the teachings of Stokes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to labeled the probes of Robledo with digoxigenin in order to have provided an effective means for facilitating the detection of *Perkinsus* nucleic acids.

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state that the Robledo reference is not prior art to the claimed invention because Applicants have provided a Declaration establishing that the cited publication describes their own work. However, as discussed above, the Declaration of Dr. Vasta does not address the absence of the inventors Adam G. Marsh and Anita C. Wright from the Robledo et al (2000) reference and is not sufficient to remove the Robledo reference as prior art.

11. Claim 3 and newly added claim 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robledo (1999/references "AX") in view of the Stratagene Catalog (1988).

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus marinus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 1 (see Figure 2). Robledo also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 4 and 5 and of a length of 21 nucleotides (see Table 1). The nucleic acid and primers of

Robledo comprise fragments of the sequence of SEQ ID NO: 18. Robledo does not teach packaging the primers in a kit.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses the general concept of kits for performing nucleic acid hybridization methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers of Robledo in a kit for the expected benefits of convenience and cost-effectiveness for practitioners of the art wishing to amplify and detect *Perkinsus* nucleic acids.

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state the claims have been amended to recite SEQ ID NO: 18 and thereby the combined references do not teach the use of SEQ ID NO: 18 in a kit. However, the claims are not limited to kits comprising SEQ ID NO: 18. Rather, claim 3 and newly added claim 31 are broadly drawn to kits containing a nucleic acid comprising a sequence of (i.e., a fragment or any portion of) SEQ ID NO: 18. As discussed above, the language "having a nucleic acid sequence selected from the group of sequences of SEQ ID NO: 18" has been interpreted to mean comprising a portion of a nucleic acid sequence found within SEQ ID NO: 18. Such a sequence may be of any length and may be flanked by any number of nucleotides of any identity.

12. Claims 3 and newly added claim 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marsh in view of the Stratagene Catalog (1988).

Marsh teaches isolated nucleic acids comprising the NTS region of *Perkinsus marinus*. In particular, the nucleic acid of Marsh comprises a sequence identical to present SEQ ID NO: 1 (see Figure 1). Marsh also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 4 and 5 and of a length of 21 nucleotides (see page 577). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Marsh have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 18. Marsh teaches using the nucleic acid as a probe to detect *Perkinsus* sequences, but does not teach packaging the primers in a kit.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses the general concept of kits for performing nucleic acid hybridization methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers of Marsh in a kit for the expected benefits of convenience and cost-effectiveness for practitioners of the art wishing to amplify and detect *Perkinsus* nucleic acids.

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state the claims have been amended to recite SEQ ID NO: 18 and thereby the combined references do not teach the use of SEQ ID NO: 18 in a kit. However, the claims are not limited to kits comprising SEQ ID NO: 18. Rather, claim 3 and newly added claim 31 are broadly drawn to kits containing a nucleic acid comprising a sequence of (i.e., a fragment or any portion of) SEQ ID NO:

18. As discussed above, the language “having a nucleic acid sequence selected from the group of sequences of SEQ ID NO: 18” has been interpreted to mean comprising a portion of a nucleic acid sequence found within SEQ ID NO: 18. Such a sequence may be of any length and may be flanked by any number of nucleotides of any identity.

13. Claims 3 and newly added claim 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robledo (2000/reference AY) in view of the Stratagene Catalog (1988).

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus atlanticus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 18 (see Figure 2). Robledo also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 8 and 9 and of a length of 20 and 22 nucleotides, respectively (see page 974). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 18. Robledo does not teach packaging the primers in a kit.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses the general concept of kits for performing nucleic acid hybridization methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers of Robledo in a kit for the expected benefits of

convenience and cost-effectiveness for practitioners of the art wishing to amplify and detect *Perkinsus* nucleic acids.

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state that the Robledo reference is not prior art to the claimed invention because Applicants have provided a Declaration establishing that the cited publication describes their own work. However, as discussed above, the Declaration of Dr. Vasta does not address the absence of the inventors Adam G. Marsh and Anita C. Wright from the Robledo et al (2000) reference and is not sufficient to remove the Robledo reference as prior art.

14. Claims 2, 9-11, 13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable Robledo (GenBank Accession No. AF140295/NCBI Database, April 17, 2000) in view of Marsh.

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus atlanticus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 18. This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18. Robledo does not teach labeling the nucleic acids or generating primers from fragments of the nucleic acids.

However, Marsh also teaches isolated nucleic acids comprising the NTS region of *Perkinsus marinus*. Marsh teaches labeling the NTS sequences so that they may be used as probes. Accordingly, it would have been obvious to one of ordinary skill in the

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art at the time the invention was made to have labeled the nucleic acids of Robledo in order to have allowed for the use of the nucleic acids as probes for detecting Perkinsus sequences. Furthermore, Marsh also teaches methods for synthesizing oligonucleotides comprising NTS sequences wherein the methods comprise isolating DNA from an organism, amplifying NTS sequences, determining the sequence of the amplified nucleic acids and preparing primers to the nucleic acids. Marsh (page 577) teaches preparing primers designed for the NTS region using the Whitehead PRIMER program and exemplifies 2 NTS primers of a length of 21 nucleotides. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to performed methods for synthesizing nucleic acids comprising a sequence of the NTS of Robledo and particularly to have synthesized NTS primers in order to have provided oligonucleotides and primers useful for amplifying and detecting Perkinsus sequences.

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state that the Robledo reference is not prior art to the claimed invention because Applicants have provided a Declaration establishing that the cited publication describes their own work. However, as discussed above, the Declaration of Dr. Vasta does not address the absence of the inventors Adam G. Marsh and Anita C. Wright from the GenBank reference and is not sufficient to remove the Robledo reference as prior art.

15. Claims 3 and newly added claim 31 are rejected under 35 U.S.C. 103(a) as being unpatentable Robledo (GenBank Accession No. AF140295/NCBI Database, April 17, 2000) in view of Marsh and further in view of the Stratagene Catalog.

The teachings of Robledo and Marsh are presented above. The combined references do not teach packing primers comprising sequences of GenBank Accession No. AF140295 into a kit.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses the general concept of kits for performing nucleic acid hybridization methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers comprising sequences of GenBank Accession No. AF140295 in a kit for the expected benefits of convenience and cost-effectiveness for practitioners of the art wishing to amplify and detect *Perkinsus* nucleic acids.

RESPONSE TO ARGUMENTS:

In the response filed October 2, 2003, Applicants state that the Robledo reference is not prior art to the claimed invention because Applicants have provided a Declaration establishing that the cited publication describes their own work. However, as discussed above, the Declaration of Dr. Vasta does not address the absence of the

inventors Adam G. Marsh and Anita C. Wright from the GenBank reference and is not sufficient to remove the Robledo reference as prior art.

16. THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 21-30 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-17 of prior U.S. Patent No. 6,326,485. This is a double patenting rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. This phone number will be changed after January 13 to (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
January 7, 2003


CARLA J. MYERS
PRIMARY EXAMINER